K021042

MAY 15 2002

Thermo Forma

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Marietta, OH 45750

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510(k) SUMMARY

Submitted By: Richard L. Miller, CQE
Manager of Regulatory Compliance
Thermo Forma, Inc.
401 Millcreek Road
Marietta, Ohio 45750

March 28, 2002

Names of Devices:

Trade Name:	CryoMed ® IVF Controlled Rate Freezer
Common/Usual Name:	IVF Controlled Rate Freezer
Classification Name:	IVF Controlled Rate Freezer 21 CFR 884.6120

Predicate Device: 63 FR 48428, September 10, 1998

Device Description:
The CryoMed ® controlled rate freezers are bench top units. They control temperature and temperature change rate through the use of liquid nitrogen (LN_2), an electric heater and an air-circulating fan. Freezing parameters and alarm functions are controlled by a microprocessor built into the controlled rate freezer itself. The freezer is supplied with several preloaded freezing profiles as well as allowing the user to define their own profiles. Optional PC resident software, supplied with each unit, allows user defined programs to be written on a personal computer and downloaded to the freezer. The freezer then stores these parameters in its memory and takes over control of the run.

Intended Use:
The Thermo Forma CryoMed ® Controlled Rate Freezers are intended to be used to freeze gametes and/or embryos at a user determined rate. This device is not intended for long-term storage.

Substantial Equivalence:
In accordance with the Final Rule on reclassification of Medical Devices Used for In Vitro Fertilization, Thermo Forma cites the Final Rule as support for substantial equivalence.

Discussion of Tests and Test Results:
Thermo Forma's CryoMed ® Controlled Rate Freezers were subjected to electrical safety, electromagnetic compatibility and operating performance tests. The freezers passed all these tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2002

Richard L. Miller, CQE
Manager of Regulatory Compliance
Thermo Forma, Inc.
P.O. Box 649
401 Millcreek Road
MARIETTA OH 45750

Re: K021042
Trade/Device Name: Thermo Forma Controlled Rate Freezers
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: 85 MQG
Dated: March 27, 2002
Received: April 1, 2002

Dear Mr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021042

Device Name: IVF Controlled Rate Freezer

Indications For Use:

The intended use of these freezers is to freeze gametes and/or embryos. The functionality of a controlled rate freezer is designed to allow the user to select the desired cooling rate and temperature, for the purpose of improved viability.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Lagerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021042